

University of Groningen

Telemedicine in patients with peripheral arterial disease

Haveman, Marjolein E.; Kleiss, Simone F.; Ma, Kirsten F.; Vos, Cornelis G.; Unlu, Cagdas; Schuurmann, Richte C. L.; Bokkers, Reinoud P. H.; Hermens, Hermie J.; De Vries, Jean-Paul P. M.

Published in:
Expert review of medical devices

DOI:
[10.1080/17434440.2019.1649595](https://doi.org/10.1080/17434440.2019.1649595)

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version
Publisher's PDF, also known as Version of record

Publication date:
2019

[Link to publication in University of Groningen/UMCG research database](#)

Citation for published version (APA):

Haveman, M. E., Kleiss, S. F., Ma, K. F., Vos, C. G., Unlu, C., Schuurmann, R. C. L., Bokkers, R. P. H., Hermens, H. J., & De Vries, J-P. P. M. (2019). Telemedicine in patients with peripheral arterial disease: is it worth the effort? *Expert review of medical devices*, 16(9), 777-786.
<https://doi.org/10.1080/17434440.2019.1649595>

Copyright

Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license. More information can be found on the University of Groningen website: <https://www.rug.nl/library/open-access/self-archiving-pure/taverne-amendment>.

Take-down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): <http://www.rug.nl/research/portal>. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.



Telemedicine in patients with peripheral arterial disease: is it worth the effort?

Marjolein E. Haveman, Simone F. Kleiss, Kirsten F. Ma, Cornelis G. Vos, Çağdaş Ünlü, Richtel C.L. Schuurmann, Reinoud P.H. Bokkers, Hermie J. Hermens & Jean-Paul P.M. De Vries

To cite this article: Marjolein E. Haveman, Simone F. Kleiss, Kirsten F. Ma, Cornelis G. Vos, Çağdaş Ünlü, Richtel C.L. Schuurmann, Reinoud P.H. Bokkers, Hermie J. Hermens & Jean-Paul P.M. De Vries (2019): Telemedicine in patients with peripheral arterial disease: is it worth the effort?, Expert Review of Medical Devices, DOI: [10.1080/17434440.2019.1649595](https://doi.org/10.1080/17434440.2019.1649595)

To link to this article: <https://doi.org/10.1080/17434440.2019.1649595>



© 2019 The Author(s). Published by Informa UK Limited, trading as Taylor & Francis Group.



[View supplementary material](#)



Published online: 05 Aug 2019.



[Submit your article to this journal](#)



Article views: 262



[View related articles](#)



[View Crossmark data](#)

REVIEW



Telemedicine in patients with peripheral arterial disease: is it worth the effort?

Marjolein E. Haveman^a, Simone F. Kleiss^a, Kirsten F. Ma^a, Cornelis G. Vos^b, Çağdaş Ünlü^c, Richté C.L. Schuurmann^a, Reinoud P.H. Bokkers^d, Hermie J. Hermens^e and Jean-Paul P.M. De Vries^a

^aDepartment of Surgery, Division of Vascular Surgery, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands;

^bDepartment of Surgery, Martini Hospital, Groningen, The Netherlands; ^cDepartment of Vascular Surgery, Northwest Clinics, Alkmaar, The Netherlands; ^dDepartment of Radiology, Medical Imaging Center, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands; ^eDepartment of Biomedical Signals and Systems, Telemedicine cluster, University of Twente, Enschede, the Netherlands

ABSTRACT

Introduction: For patients with peripheral arterial disease (PAD), the various components of telemedicine, such as telemonitoring, telecoaching, and teleconsultation, could be valuable in daily management. The objective of this review was to give an overview of the current use of telemedicine interventions in PAD.

Areas covered: A literature search was performed for studies that evaluated patients with PAD of the aorto-pedal trajectory, who were monitored by telemedicine and acted upon accordingly. The primary outcome was health-related outcomes. The studies that were found focused mainly on wearable activity monitoring and telecoaching in PAD ($n = 4$) or wound monitoring after vascular surgery ($n = 2$). Main results indicate that telemedicine interventions are able to detect (post-operative) complications early, improve functional capacity and claudication onset time, and improve PAD patients' quality of life.

Expert opinion: The use of telemedicine in PAD patients is still an under-explored area. Studies investigating the use of telemedicine in PAD are very limited and show varying results. Owing to its high potential in improving physical ability, lifestyle coaching, and timely detection of deterioration, future research should focus on proper implementation of telemedicine in PAD patients, including clinical and feasibility outcomes, effect on workload of nurses, and cost-efficiency.

ARTICLE HISTORY

Received 8 May 2019

Accepted 25 July 2019

KEYWORDS

Telecoaching; telemedicine; telemonitoring; peripheral arterial disease; vascular surgery

1. Introduction

Telemedicine is the use of telecommunications technology to provide health care from a distance. Its implementation in medical care has become increasingly popular in recent years, especially in patients with chronic diseases [1–4]. In chronic heart disease, telemedicine is associated with a reduction of hospitalization and readmissions, lower mortality, and improved clinical outcome and cost-effectiveness of care [5]. The use of telemedicine in health care meets the tendency toward personalized medicine and the need to control rising health-care costs, including an individual approach and migration of care toward home with the use of remote monitoring, education of patients, and virtual visits to medical professionals [2].

Telemedicine can be divided into educational or supportive websites, telecoaching, telemonitoring, telerehabilitation, and teleconsultation [6]. Various aspects, such as telemonitoring, telecoaching, and teleconsultation, can be potentially important tools in the treatment of patients with peripheral arterial disease (PAD). Patients with PAD are usually old, frail and multimorbid, and could benefit from monitoring of health parameters and vascular risk factors. Moreover, these patients frequently have mobility issues and could thus particularly

benefit from techniques that reduce the need for hospital visits. Possible targets for monitoring include regulation of hypertension, weight, renal function, diabetes management, hyperlipidemia control, smoking behavior, and wound status. In addition, telemedicine could be used to improve secondary prevention and lifestyle coaching.

In this systematic review, we summarize the currently available literature on the application of telemedicine in patients with PAD.

2. Methods

This report was written in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [7]. The review protocol was prospectively registered in the PROSPERO database (ID: CRD42019132621).

2.1. Literature search

PubMed, CINAHL (via EBSCO), and Embase databases were searched for eligible articles published between 1 January 2009, and 1 March 2019. Search terms describing telemedicine were combined with terms for arterial diseases, including controlled

Article highlights

- Currently reported telemedicine interventions in patients with peripheral arterial disease focus on wearable activity monitoring, tele-coaching, teleconsultation, and wound monitoring.
- Only six recent studies describe health outcomes after telemedicine interventions in patients with peripheral arterial disease; however, evidence for additional clinical value is based on limited numbers of patients, and no robust conclusions can be drawn from the literature.
- Increasing technological possibilities for telemedicine offer great potential in (self-)care of patients with peripheral arterial disease, justifying further research on the implementation of telemedicine in these patients.

terms (Medical Subject Headings in PubMed, Subject Headings in CINAHL and Emtree in Embase) and also free-text terms. The full search strategy is added as Supplementary. Additional studies were identified by reviewing the reference lists of the studies found in the search.

2.2. Selection criteria

Articles were eligible according to the PICO framework if they included patients with PAD of the aorta-pedal trajectory (P), a telemedicine intervention based on patient monitoring (I), either a control group receiving standard of care or no control group (C), and patient outcome measures as described in [section 2.4](#) (O). Telemonitoring was defined as in-hospital or transmural monitoring of patients through wireless measurement of vital parameters or activity or through electronic questionnaires regarding health, based on which coaching or feedback might be provided. Telemonitoring intervention is defined if telemonitoring is used to intervene if necessary. Exclusion criteria were: no PAD patients; no telemonitoring intervention; no outcome measures as described in [section 2.4](#); patients younger than 18 years old; or no full-text available. Access to full-text articles was gained through our medical library or in case of unavailability through direct contact with the author. If no full text was available after these attempts, articles were excluded. There were no restrictions on the setting of telemedicine (in-hospital, long-term, peri-operative, and at home), language or sample size. Because the subject of telemedicine is yet a new and growing field of expertise, we decided not to limit the search to specific study types, with the exception of case reports, reviews, commentaries, letters to the editor, or conference abstracts.

2.3. Data collection and quality assessment

After duplicates were removed, two authors (MH, SK) independently screened the titles and abstracts of the identified studies for relevance. The full text of the remaining relevant studies were read by two authors (MH, SK), and a final selection of relevant studies was made. In case of discrepancies between the two reviewers, a third author was consulted (KM). The methodological quality of the randomized and non-randomized studies was assessed using the checklist described by Downs and Black [8]. Two reviewers (MH, RB)

independently evaluated the study quality, and discrepancies were discussed until consensus was reached. The thresholds used to classify study quality were good (9–16), moderate (17–23), and poor (below 14) [6].

2.4. Outcome measures and data analysis

The primary outcome measures were disease-specific health-related outcomes (wound) complications, and quality of life (QoL). Secondary outcomes were office visits, hospital readmissions, and hospital length of stay. Data extracted included the year of publication, study design, study period, study inclusion criteria, age of included patients, sample size, control group, interventions, telemedicine instruments, and outcome measures, as mentioned. Reported baseline and post-interventional change in outcome measures were extracted to compare the intervention group with the control group.

The heterogeneity in study design, type of telemedicine applied, and outcome measures described precluded pooling of data or performing a meta-analysis. Therefore, we present a narrative summary of the included studies consisting of study characteristics and outcomes. Subgroups of different intervention types are presented separately.

3. Results

3.1. Description of study selection

A systematic literature search identified 1249 records ([Figure 1](#)). After the duplicates were removed, 872 records remained for the title and abstract screening. From these, 854 were excluded because they did not meet the inclusion criteria, mainly because other patient populations were described (mostly carotid or cerebral artery diseases) or a telemonitoring intervention was absent. Full-text assessment of the remaining 18 articles resulted in six articles fulfilling the inclusion criteria of this review [17,24–28]. The characteristics of the included studies are summarized in [Table 1](#). [Table 2](#) reports the outcomes of the included studies. The excluded full-text papers with the reason for exclusion are listed in [Table 3](#).

The included studies described a total of 477 patients, with a mean sample size of 80 patients (range, 19–200), and were all published in 2018 or 2019. The ages of these patients ranged from 62.5 to 70.2 years. Five randomized controlled trials (RCTs) were included [17,24,25,27,28] and one prospective cohort study [26]. Two studies were focused on telemonitoring tools to monitor surgical site infections (SSIs) [17,26] and post-discharge complications [17] after vascular surgery. The four other RCTs included telecoaching tools in patients with PAD who underwent home-based exercise intervention [24,27,28] or a self-management program [25].

3.2. Methodological quality of included studies

The study quality scores are reported in [Table 1](#). The table with the scoring for the different categories of the Downs and Black checklist is displayed in Supplementary Table I. No studies were judged as having a poor study quality. Three were of moderate quality and three of high study quality. Most studies

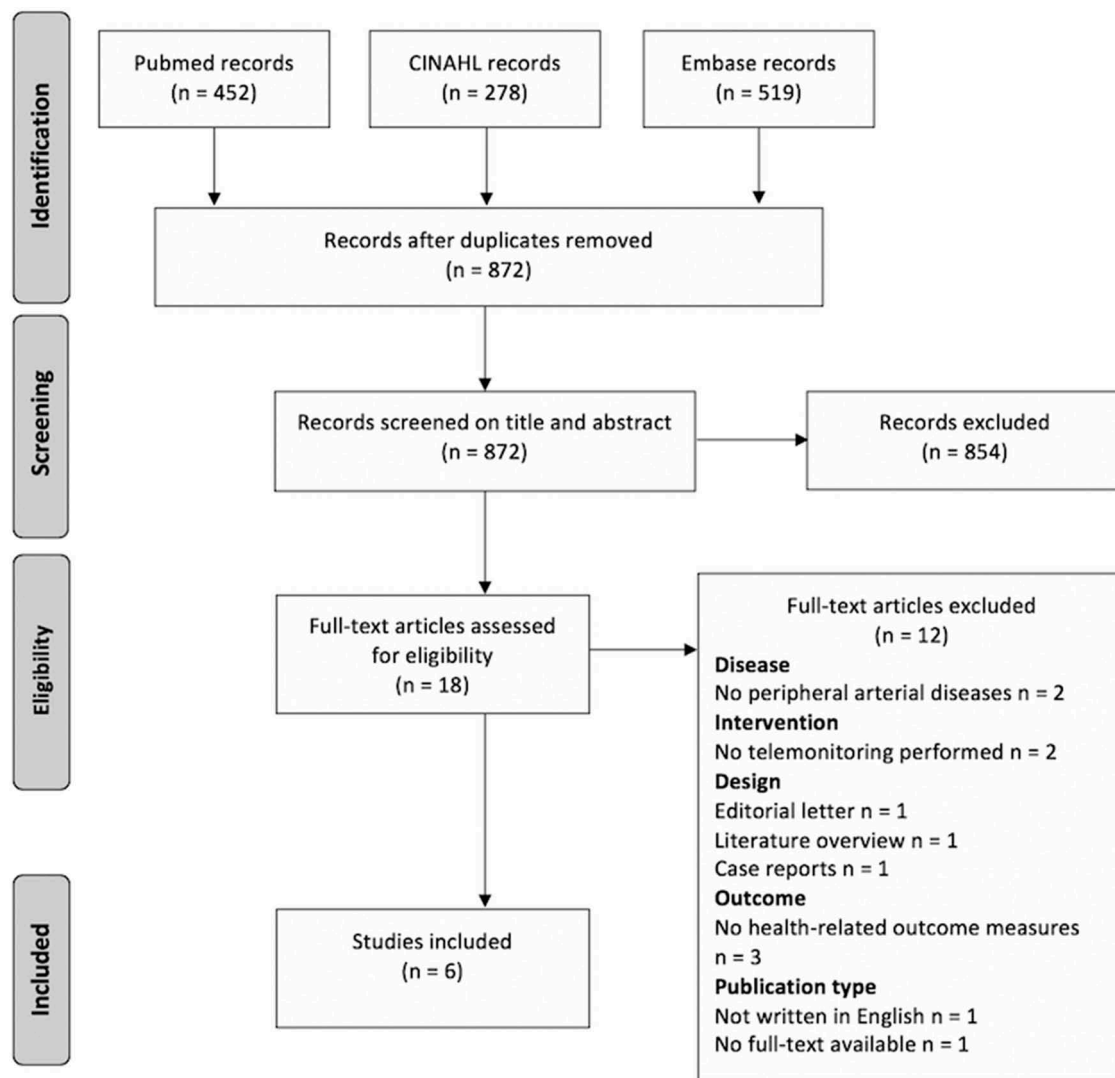


Figure 1. PRISMA flow diagram of study selection.

scored low at blinding subjects and clinicians to the intervention and outcome measurement and at making clear which analysis was not planned at the outset of the study.

3.3. Post-operative telemonitoring

One feasibility study and one RCT on post-operative telemonitoring were identified.

Gunter et al. [26] evaluated the feasibility and use of a WoundCheck app in a prospective analysis of 47 consecutive patients, of which 40 completed a 14-day post-operative follow-up protocol. All patients underwent a vascular surgical procedure with an incision of at least 3 cm and were trained to use the WoundCheck app during admission. Patients used the app to send a daily photo of the wound and to answer questions about their recovery. During follow-up, eight SSIs were recorded, seven of which were detected using the WoundCheck app, with no false positives. Three patients were readmitted: one after falling on the amputation stump, one for respiratory failure, and one because of an unresolved

SSI after antibiotic therapy. The authors concluded that the protocol including the WoundCheck app can be completed by patients and health-care providers. In addition, the app led to the detection and treatment of SSIs before routine follow-up visits occurred in standard care.

Moussa et al. [17] evaluated clinical outcomes, use, feasibility, patient satisfaction, and QoL after vascular procedures with infrainguinal incisions in patients receiving TeleHealth Electronic Monitoring (THEM) or standard care. THEM comprises daily measurements of blood pressure, heart rate, oxygen saturation, weight, and temperature, which are manually registered by the user in a tablet and monitored by a health-care provider for abnormalities. Of 30 patients, 16 were randomly assigned to the intervention group and instructed to record the THEM parameters until the first follow-up visit. The tablet was also used for daily and weekly quiz questions and system alerts based on measurements or quiz answers. Care managers monitored values daily, contacted patients based on the system alerts, and requested pictures of the surgical site for assessment and comparison. No significant differences

Table 1. Study characteristics.

Study characteristics				Patients			Intervention	
First author, year of publication	Design	Study period	Study quality Downs & Black	Inclusion criteria	Age		Control group	Description
					Mean (SD) or median [range], y	Intervention/control No.		
Post-operative monitoring of 30 days outcome measures Mousa, 2019	RCT	NR	25/28	Vascular procedure with infrainguinal incision	62.5 (7.2)	16/15	Standard of care	Daily home monitoring of vital parameters and questionnaires about wound healing and recovery until the first follow-up visit
Gunter, 2018	Feasibility study	2016	15/28	Vascular surgery patients with a surgical incision >3 cm, admission at least 2 days	63 [35–89]	40	No control	Daily submission of pictures of surgical wound and a brief summary about recovery for 2 weeks after surgery
Telecoaching and telemonitoring in PAD patients Duscha, 2018	RCT	NR	21/28	PAD patients with intermittent claudication and ABI <0.90	69.4 (8.4)	10/9	Standard of care	Weekly e-mails with PAD tips and monthly feedback and personalized exercise prescription based on steps per day for 12 weeks
McDermott, 2018	RCT	2015–2017	24/28	PAD patients with ABI ≤0.90, lower extremities arterial stenosis ≥70%, or decrease of ABI by 20% at heel-rise test	70.2 (10.4)	99/101	Standard of care	Weekly to monthly telephone coaching on exercise goals and challenges with review of wearable activity monitor data during 9 months
Davins Riu, 2018	RCT	NR	19/28	PAD patients with intermittent claudication confirmed by a vascular surgery specialist	NR	75/75	Standard of care	Completion of a PAD-related dynamic questionnaire every 3 months for self-checks and advised to request additional visits over a 12-month period
Normahani, 2018	RCT	2013–2014	20/28	PAD patients with intermittent claudication determined by clinical assessment and Duplex ultrasound imaging	69.1 (10.4)	20/17	Standard of care	Wrist-worn activity monitor with real-time feedback about progress towards daily goals reviewed during follow-up at 3, 6 and 12 months
								CONTECI program on computer or mobile device
								Nike+ FuelBand with NikePlus on paired mobile device or computer

RCT = randomized controlled trial, SD = standard deviation, PAD = peripheral arterial disease, ABI = ankle-brachial index, NR = not reported

Table 2. Study outcomes.

First author, year of publication	Type of outcome measure	Measuring instrument	Follow-up moment	Intervention group		Control group		p-value ^a
				Baseline	Change at follow-up	Baseline	Change at follow-up	
				Mean (SD) or median [IQR]	No. or mean (SD) or median [IQR]	Mean (SD) or median [IQR]	No. or mean (SD) or median [IQR]	
Post-operative monitoring of 30-day outcome measures Mousa, 2019	30-days readmission (No.)	NA	30 days post-discharge	NA	4	NA	2	0.657 ^b
	Surgical site infection (No.)	NR	30 days post-discharge	NA	5	NA	1	0.175 ^b
	QoL	SF-8 Physical function score	NR	28.7	7.5	35.07	1.1	0.002 ^{*b}
	Office visits (No.)	NA	NR	NA	2	NA	1	1.000 ^b
Gunter, 2018	30-days readmission (No.)	Medical record	30 days post-discharge	NA	3	NA	NA	NA
	Surgical site infection (No.)	Medical record	30 days post-discharge	NA	8	NA	NA	NA
Telecoaching and telemonitoring in PAD patients Duscha, 2018	Claudication onset time (s)	Treadmill	12 weeks	320 (226)	204.6 (280.6)	252 (256)	−21.0 (142.7)	<0.05*
	VO ₂ max (ml/kg/min)	Treadmill with 12-leads ECG and TrueMax 2400	12 weeks	15.2 (4.27)	20.3 (26.4) %	14.3 (5.4)	1.0 (6.9) %	<0.05*
	Peak walking time (s)	Metabolic Cart gas analysis	12 weeks	596 (271)	227.6 (286.5)	546 (394)	22.4 (107.7)	<0.06*
	Steps/day (No.)	Fitbit Charge	12 weeks	6829 (3370)	291 (916)	5011 (1822)	37 (1403)	NR
	6-minute walking distance (m)	100ft hallway	9 months	330.5 (100.2)	5.5 [−8.7 to 19.7]	336.2 (96.6)	14.4 [0.5 to 28.3]	0.31
	Physical functioning	SF-36 Physical function score	9 months	35.8 (9.4)	0.4 [−1.5 to 2.4]	36.9 (9.0)	1.8 [0 to 3.7]	0.24
	Mobility	PROMIS	9 months	33.3 (5.3)	−0.3 [−1.3 to 0.7]	33.8 (5.3)	−0.7 [−1.7 to 0.3]	0.47
	Pain interference	PROMIS	9 months	56.4 (8.4)	0.7 [−1.1 to 2.6]	56.7 (7.5)	−2.8 [−4.6 to −1.0]	0.002*
	Steps/day (No.)	Fitbit Zip	192 to 252 days	NA	−394 [−972 to 185]	NA	NA	NA
	QoL	EuroQoL-5D	12 months	67.87	72.25	64.4	67.24	0.195 ^b
Davins Riu, 2018	Visits control (No.)	NA	12 months	NA	2.23 (0.6)	NA	0.27 (0.73)	0.000 ^{ab}
	Visits ED (No.)	NA	12 months	NA	0.017 (0.48)	NA	0.19 (0.48)	0.017 ^{ab}
	Admissions (No.)	NA	12 months	NA	0.05 (0.29)	NA	0.04 (0.267)	0.655 ^b
	Max walking distance (m)	Treadmill	3 months	80 [50–117]	16 [−3 to 58]	68 [50–70]	20 [−5 to 48]	0.78
	Max walking distance (m)	Treadmill	6 months		82 [39 to 110]		−5 [−8 to 33]	0.009*
	Max walking distance (m)	Treadmill	9 months		69 [37 to 144]		8 [−9 to 31]	0.011*
	Claudication distance (m)	Treadmill	3 months	40 [24–61]	12 [1 to 23]	36 [26–41]	10 [−6 to 29]	0.32
	Claudication distance (m)	Treadmill	6 months		63 [34 to 95]		11 [5 to 21]	0.002*
	Claudication distance (m)	Treadmill	9 months		38 [24 to 162]		0.04 [−0.28 to 0.32]	0.011*
	QoL	VascuQoL	3 months	4.7 [3.9–5.2]	0.78 [0.37 to 0.95]	4.5 [2.8–5.0]	0.2 [0 to 0.6]	0.004*
Normahani, 2018	QoL	VascuQoL	6 months		0.9 [0.5 to 1.2]		0.1 [−0.2 to 0.6]	0.031*
	QoL	VascuQoL	9 months		0.8 [0.5 to 1.5]			0.065

QoL = quality of life, ED = emergency department, NR = not reported, NA = not applicable.

^aDifferences between both groups in change scores between pre- and post-intervention.^bDifferences between both groups in post-intervention scores.^{*}Significantly different between both groups, $p < 0.05$.

Table 3. Excluded studies.

First author, year	Sample size	Study design	Exclusion reason
Mullenheim, 2018	NA	Comment	Design: editorial letter
Shalan, 2018	NR	App design	No telemonitoring intervention
Cornelis, 2017	99	Questionnaire	No telemonitoring intervention
Michard, 2017	NA	Overview	Design: literature overview
Gunter, 2016	9	App design	No health-related outcome measures
Mercer, 2016	32	Focus groups	No peripheral arterial diseases
Greving, 2015	330	RCT	No health-related outcome measures
Dhukaram, 2012	34	Focus groups	No peripheral arterial diseases
Boyes, 2009	2	Case reports	Design: case reports
Unknown	NA	NA	No full-text available
Wu, 2016	NA	Prototype development	No health-related outcome measures
Garcia, 2015	5	App design	No health-related outcome measures

NA = not applicable, NR = not reported, RCT = randomized controlled trial.

were found between the groups in the number of readmissions within 30 days, office visits, or SSI, as reported in Table 2. However, care managers identified more wound problems in the THEM group, but without significance (5 vs. 1, $p = 0.175$). Patients in the THEM group had a significantly more pronounced increase between the pre- and post-operative QoL subscales of physical function (7.5 vs. 1.1, $p = 0.002$) and physical role (8.7 vs. 1.1, $p = 0.001$) as measured with the 8-Item Short Form Health Survey. The authors concluded that THEM was technically feasible, improved patient satisfaction, and successfully merged remotely generated information with patient management.

3.4. Telecoaching in PAD

Four RCTs were identified that investigated the use of telemedicine in patients with PAD.

Davins Riu et al. [25] created a telehealth program called Control Telehealth Claudication Intermittent (CONTECI) to improve patient education, empowerment, and self-management. In this RCT, they assessed the efficacy of CONTECI as a monitoring tool in PAD patients with intermittent claudication over 12 months in clinical aspects (walking distance, Fontaine classification, number of surgical interventions), patient satisfaction, and QoL. Of the 150 included patients, 75 were randomly assigned to the intervention group and 75 to the control group. The intervention group used the CONTECI program from a computer or mobile device every 3 months to answer a dynamic questionnaire based on which they were advised to continue as before or to request a visit. The control group was monitored during standard visits every 6 months. QoL improved in both groups and improved significantly in the intervention group between baseline and 12 months' follow-up (67.9 vs. 72.3, $p = 0.047$). However, no significant differences in QoL at 12 months were found between the two groups ($p = 0.195$). Control visits were reduced by 95.95% in the intervention group, and therefore, the frequency of control visits was significantly lower than in the control group (2.2 ± 0.6 vs. 0.3 ± 0.7 , $p = 0.000$). There were fewer emergency department visits in the intervention group compared with the control group (0.017 ± 0.48 vs. 0.19 ± 0.48 , $p = 0.017$); however, these patients visited sooner in case of a complication than patients from the control group (7.9 vs. 53.9 days, $p = 0.016$). No differences were

found between the groups regarding the clinical variables of walking distance, claudication distance, and need for surgery. The authors concluded that the use of the CONTECI program is feasible, promotes patient expertise, and is of added value without clinical inferiority to conventional management.

Duscha et al. [28] investigated the effect of a 12-week home-based mobile health intervention on the functional capacity and physical activity patterns of sedentary patients with intermittent claudication. Before randomization and during weeks 11 and 12, all patients wore a Fitbit Charge (Fitbit, Inc., San Francisco, CA) device for activity tracking. The study randomized 20 patients between intervention and standard of care. The intervention group ($n = 10$) received weekly e-mails with a PAD tip and monthly feedback with exercise prescriptions based on the number of steps per day measured with the Fitbit. Patients in the intervention group showed significantly more improvement compared with the control group in differences between pre- and post-intervention claudication onset time (204.6 ± 280.6 s vs. -21.0 ± 142.7 s, $p < 0.05$), maximum oxygen consumption volume ($20.3\% \pm 26.4\%$ vs. $1.0\% \pm 6.9\%$, $p < 0.05$), and peak walking time (227.6 ± 286.5 s vs. 22.4 ± 107.7 s, $p < 0.06$). Daily step counts were not significantly different between the groups. These findings indicate that a mobile health intervention as an alternative to supervised site-based exercise therapy for PAD patients might be effective and additionally could provide a long-term solution after completing such a supervised program, especially for those not able to attend on-site supervised exercise therapy.

McDermott et al. [27] also developed a home-based monitored exercise program for PAD patients. The aim of their trial was to investigate whether a 9-month intervention, based on telephone coaching and wearable activity monitoring, could improve walking endurance and patient-reported outcomes. The intervention group comprised 97 randomly assigned patients who received individualized coaching on exercise goals and challenges. A website accessible to both patient and coach was used to enter exercise goals by a coach during telephone contact (subsequently once weekly, every 2 weeks, or every month over a 9-month period), enter the walking exercise minutes by the participant; and upload data from a Fitbit Zip (Fitbit, Inc., San Francisco, CA) device via Bluetooth. The control group ($n = 101$)

received standard of care and were contacted by phone every 3 months to obtain information on physical activity and walking exercise frequency. The increase in the number of episodes of walking exercise per week was significantly greater in the intervention group than in the control group at 3 months (2.0 ± 3.7 vs. 0.7 ± 2.5 , $p = 0.005$) and 6 months of follow-up (2.8 ± 7.3 vs. 0.9 ± 3.3 , $p = 0.045$) but not at 9 months of follow-up (1.9 ± 5.0 vs. 0.8 ± 2.9 , $p = 0.09$). No significant differences were found between both groups at 9 months of follow-up in the 6-min walking distance or physical functioning score on the 34-Item Short Form Health Survey. Remarkably, the control group reported a significantly greater decrease in the PROMIS-measured pain interference score for daily activities at the 9-month follow-up compared with the intervention group ($-2.8 [-4.6$ to $-1.0]$ vs. $0.7 [-1.1$ to $2.6]$, $p = 0.002$). The authors concluded that their home-based exercise intervention with telephone counseling and wearable activity monitoring without periodic onsite visits did not improve walking performance in patients with PAD, partly because the counseling was too infrequent.

Normahani et al. [24] conducted a pilot RCT to investigate the effect of a feedback-enabled wearable activity monitor on walking distances and QoL in patients with intermittent claudication. The study randomized 37 patients to an intervention group ($n = 20$) or a control group ($n = 17$). During 12 months, patients in the intervention group wore a Nike+ FuelBand (Nike, Inc., Beaverton, OR) around their wrist that recorded their activity and gave real-time feedback about the progression toward daily goals, so-called 'fuel points', a measure for overall movement and activity. Daily goals were adjusted at each follow-up visit at 3, 6, and 12 months based on the percentage of days that the fuel points targets were achieved. Maximum walking distances (MWD), claudication distance (CD), and scores on the Vascular Quality of Life (VascuQoL) questionnaire (scale 1–7) were collected before randomization and during each follow-up visit. Patients in the intervention groups showed significant improvements between baseline and 3-, 6-, and 12-month MWD, CD, and VascuQoL, whereas patients in the control group did not. At 3 months, however, the magnitude of change did not differ between the intervention and control group in MWD (15.5 vs. 20 m, $p = 0.78$) and CD (11.5 vs. 8 m, $p = 0.32$), but differed significantly in VascuQoL (0.78 vs 0.04, $p = 0.004$). At the 6- and 12-month follow-up, the magnitude of change compared with baseline was significantly higher in the intervention group than in the control group. The authors concluded that wearable activity monitors promote physical activity and might be beneficial in improving physical function and QoL in PAD patients.

4. Discussion

Rapid development of new technologies offers many advantages of telemedicine in patients with PAD. Telemedicine has the potential to improve clinical outcome, QoL, and cost-effectiveness of health-care interventions; however, the literature on its application is scarce. This systematic review identified six studies focused mainly on telemonitoring and telecoaching. The studies indicate that telemedicine interventions can aid in the early detection of postoperative complications, improve functional capacity, reduce

claudication onset time, and improve patients' expertise and QoL. These findings, however, are based on limited numbers of patients, and the studies show conflicting results.

The aim of this review was to give an overview of the current use of telemedicine for monitoring patients with peripheral arterial disease. Since interventions for PAD patients are either supervised exercise therapy or revascularization (surgery), telemedicine applications for these patients include either monitoring of claudication exercise programs to increase walking distance or postoperative wound care and wound-related complications. The main differences between studies using one of these types of telemonitoring are the type of devices used (i.e. activity monitoring vs. application to upload wound pictures) and outcome parameters (i.e. walking performance measures vs. wound complication).

Treadmill exercises are recommended as the first line of therapy for patients with intermittent claudication because they have been shown to improve functional outcome [18]. Supervised exercise programs are preferred because unsupervised programs lack compliance [19]. Participation is still limited, however, because a supervised program requires multiple visits to an exercise center. The study of Gardner et al. showed that a step-monitored home exercise program could improve the 6-min walk distance even more than supervised exercises in these patients [20]. Calf muscle oxygen saturation, vascular function, and inflammation were also shown to improve [20].

These results were, however, not confirmed by McDermott et al. [27], who suggested that this might be due to [1] remote coaching being less potent than in-person visits [2]; a mismatch between wearable activity monitoring and exercise recommendations, because the first led to an increase in overall activity level rather than to an increase in walking exercise; and [3] too infrequent counseling. This covers important factors that might withhold the implementation of telemedicine interventions in this patient population.

Traditionally, most vascular patients are regularly monitored 6 weeks post-intervention at the out-patient clinic. This holds the risk that SSIs will be missed or diagnosed late because most infections will occur <6 weeks after the intervention. Telemedicine interventions can fill this unmet need because physicians can monitor their patients at any time. Moreover, telemedicine can reduce unnecessary visits, overcome the problem of transportation issues, and enhance self-awareness, -diagnosis, and -management in vascular patients [17,25,26,28]. What the optimal frequency is for monitoring of these patients is still questionable, however. Only one study described the monitoring of vital parameters in patients after vascular surgery. Mousa et al. [17] described the number of alerts based on these data (a total of 134); however, they did not mention the association between the alerts and caregiver contact or actual complications.

The most important methodological study limitations of the included papers are a limited number of studied patients or biases in patient inclusion and assignment to groups. Davins Riu et al. [25] concluded that their study was biased by selection of patients in which a telehealth program was most likely to benefit (patients with intermittent claudication symptoms, Fontaine stage II). Duscha et al. [28] studied a small sample size

(10 patients in the intervention arm versus 9 patients in the standard of care arm) without preconceived power calculations. The control group might have introduced biases, because of the tendency to be older and weigh more, and because the treatment assignment was not blinded. Gunter et al. [26] performed their study on a small sample size of 40 patients from a relatively homogenous population who were familiar with the technology. McDermott et al. [27] stated that their results might not be extrapolated to patients not interested in increasing exercise activity level, that the exercise intervention was not potent enough due to the absence of direct feedback on uploaded data, and that they missed substantial data for objective measurement of physical activity. The study of Mousa et al. [17] was underpowered, since only 30 of the 80 screened patients were enrolled. In the study of Normahani et al. [24], approximately half of the eligible patients declined to participate which resulted in a study population of only 37 patients. Besides, both the intervention and control group had access to a supervised exercise program (SEP), which makes it difficult to separate the effects of wearable activity monitoring from that of the SEP. However, only 15% (3 patients) of the patients from the intervention group and 29% (5 patients) from the control were enrolled in SEP.

Implementation of telemedicine interventions in patients PAD requires careful consideration. First, the balance between unsupervised periods and frequency of contact is delicate. The optimal frequency of real-life contact between patient and caregiver/coach has not yet been determined and probably cannot be completely replaced by teleconsultation.

Second, technology apprehension could play an important role in the adherence of patients to the telemedicine intervention. PAD patients are relatively old, and Cornelis et al. reported that only 26% of the PAD patients who owned a mobile phone (92 of 99) used apps [21]. Gunter et al. [26] had to exclude 32.5% of the patients in their study if they would not have provided smartphone devices for patients who did not own a suitable one. In the RCT of Mousa et al. [17], 9 of 80 patients screened for inclusion refused because of apprehension toward technology. Provision of a smartphone increases the applicability to the complete patient population; however, relying on patients' own devices provides the advantage of patients' familiarity with technology and reduces the need for extra training [25]. Another bias due to technology apprehension in telemedicine studies is that patients who are successfully recruited are more inclined to use technology, lowering the generalizability of these studies [24].

Third, compliance might also bias control groups. A pitfall of non-randomized studies is that less committed patients might prefer home-based exercise to medical center visits. Patients in the control groups might have decided to increase exercise themselves. Attention-control intervention designs might be able to overcome this bias [27].

This systematic review has limitations. The heterogeneity of the reported studies in types of intervention, outcome measures, and follow-up duration conceptually eliminated quantification of outcome heterogeneity and precluded pooling of data to perform a meta-analysis. This precludes a definitive answer to the question whether telemedicine interventions are worth the effort.

Another limitation is that only health outcome measures were included, whereas current literature regarding telemedicine in vascular patients also emphasizes the importance of feasibility (acceptability, satisfaction, etc.) for patients and caregivers. Although not incorporated in the current review, feasibility is an important factor in the implementation of telemonitoring interventions. For example, a strength of the study of McDermott et al. [27] is that they designed their exercise intervention based on patient feedback during earlier held focus groups and pilot studies in PAD patients. Noteworthy is that multiple studies report high levels of satisfaction and feelings of reassurance owing to the telemedicine intervention [17,26].

Cost-effectiveness is another relevant factor that requires more attention be given to the question of whether telemonitoring is worth the effort. In (most) studies, cost-effectiveness is mentioned as a possible advantage of telemonitoring [17,24–26]; however, data regarding cost-effectiveness are rarely provided, and mainly based on assumptions. Assessment of cost-effectiveness in healthcare should include both costs and effects within the healthcare system (such as costs of hospital stay) as well as costs outside this system (such as sick leave and travel costs) [22]. In a cost-effectiveness evaluation of a nurse-led internet-based vascular risk management program, Greving et al. [23] took into account medical costs, including medication and staff labor costs, and non-medical costs, including transportation costs and costs from paid and unpaid productivity losses. Depending on the type of telemedicine, costs of devices need to be added to such a list.

Three papers were excluded because outcome measures were the usability of a smartphone application. Shalan et al. [9] designed the YORwalk app to promote exercise in PAD patients. So far, they have tested the usability only in healthcare professionals. Garcia et al. [10] described the use of an Android application based on geolocation to control home-based exercise in five PAD patients. Gunter et al. [11] assessed the usability of the WoundCheck app, which they used for a feasibility study that was included in the current review [26]. One excluded paper described how wound progress in leg ulcer care could be followed through photographs based on two case reports [12]. Most excluded papers did not cover telemedicine interventions or did not include patients with PAD, but, for example, patient with chronic cardiovascular diseases [13,14]. This emphasizes the limited availability of reports about the use of telemedicine in PAD patients.

5. Expert opinion

Telemedicine can potentially benefit patients with PAD. There are, however, some practical issues that need to be overcome before this can successfully be implemented in daily clinical practice. Patients feel satisfied and in control at the beginning of a telemedicine intervention, but at a certain point, the intervention becomes routine and motivation decreases [25]. Game-based interventions could possibly have a positive influence on exercise attitudes in vascular patients [15]. Patient input in the development of personalized telemedicine from focus groups and pilot studies might also benefit patient

engagement towards such programs. Furthermore, Gunter et al. [26] mentioned concerns about program sustainability because of extra workload for nurses due to the in-hospital explanation of the intervention and processing of app information during their normal work activities. Sustainability depends on integration within the health-care system [26] and incorporation into a daily routine [24]. The latter is highly dependent on the type of devices used. For example, the ease of use of telemedicine tools (tablets, smartphone, applications, measurement instruments), the presence of feedback [24], and level of control will probably influence patients' adherence toward telemedicine programs.

The increasing technological potential of wearable devices as a result of the development of smaller sensors and accompanied algorithms enables the measurement of more (important) clinical parameters and, therefore, the monitoring of patients anywhere. One well-known wearable sensor is the Fitbit, which was used for activity measurements in two of our included studies [27,28]. The Fitbit is shown to be useful in other fields of medicine as well. Higher Fitbit step counts during inpatient recovery can predict lower readmission rates after metastatic peritoneal cancer surgery [16]. The Nike + FuelBand was used in one study [24] and has shown to be effective because of its ability to visualize the progress toward daily activity goals. Currently, wearable sensors are developed to monitor a range of vital parameters of patients remotely for earlier detection of post-operative deterioration [29–32]. Recently, Joshi et al. [29] presented an overview of these sensors. So far, main challenges of technology for telemonitoring are [1]: improvement of the diagnostic accuracy of these sensors and algorithms as well as the improvement of battery use and capacity [2]; the measurement of (continuous) wireless, non-invasive blood pressure [3]; adequate alarm criteria; and [4] privacy and storage of data. Electronic applications enable remote consultation between patients and health-care professionals [33] and can be used to: monitor patients well-being through wound monitoring or experience sampling (measuring experiences of daily life, such as pain and fear); inform patients about their treatment; and provide feedback and coaching.

Furthermore, telemonitoring could already be of additional value in the pre-operative phase by providing information for pre-operative screening, decision-making, and optimizing patients before surgery. The latter is known as prehabilitation, which is currently of increasing interest and is based on the 'better in, better out' principle [34]. In PAD patients, telemedicine could assist in prehabilitation by activity monitoring and coaching, for example, in patients who receive supervised exercise therapy from a physical therapist. Furthermore, mobile applications that consist of information and questionnaires can play an important role in (pre-operative) secondary risk prevention by lifestyle management coaching in this fragile population.

During the complete care trajectory of PAD patients (hospitalized or not), implementation of continuous monitoring with wearable devices could not only be used for earlier detection of deterioration but might also reduce the workload for nurses and contribute to patients' comfort and satisfaction.

However, what the optimal frequency is for monitoring and in which phase of care is unclear: continuously, hourly, daily, weekly? A pilot study in which patients are monitored in the complete peri-operative trajectory to answer these questions would be beneficial. Subsequently, the effects of implementation of telemedicine interventions in PAD patients should be further explored in larger randomized controlled trials.

It is remarkable that such an important outcome as cost-effectiveness of telemonitoring (in PAD or other patient groups) is still an underexplored area. The following factors are to be considered in future cost-effectiveness assessments. First, the economic evaluation of telemonitoring interventions requires proper implementation in healthcare. Second, the definition of a cost or effect in the evaluation of telemedicine interventions compared to usual care relies on the policy level of interest [22], whether it comprises cost-effectiveness at the level of government, hospital or patient. Third, although economic evaluation of telemedicine interventions will influence its availability in the future healthcare, the success of such implementations probably also depends on hardly measurable subjective perceptions of both caregivers and patients, such as workload and feeling of security, respectively.

Standardization in reporting on outcomes of the use of telemedicine is important and further development of telemedicine guidelines is necessary. One of the important initiatives is from the American Telemedicine Association which made progress to prioritize such guidelines and development of telemedicine standards [35]. Physicians all over the world implementing telemedicine and studying the effects of telemedicine in healthcare should be encouraged to work according to these standards. Moreover, finetuning of global telemedicine guidelines and standardization in reporting on outcomes should be on the agenda in the world-leading telemedicine conferences.

In conclusion, the use of telemedicine in PAD patients is still an under-explored area. Owing to its high potential to improve physical ability, lifestyle coaching, and detection of deterioration in these patients, future research should focus on the proper implementation of telemedicine in PAD patients, including clinical, feasibility, nurses' workload, and cost-efficiency outcome measures. Over the next years, accompanied by technological improvements, telemedicine will be integrated into many fields of health care, reinforcing the tendency toward personalized medicine, facilitating the migration of care toward home, and inhibiting rising health-care costs.

Funding

This paper was not funded.

Declaration of interest

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Reviewer disclosures

Peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

References

- Gensini GF, Alderighi C, Rasoini R, et al. Value of telemonitoring and telemedicine in heart failure management. *Card Fail Rev*. 2017;3:116–121.
- Dorsey ER, Topol EJ. State of telehealth. *N Engl J Med*. 2016;375:154–161.
- Wootton R. Twenty years of telemedicine in chronic disease. *J Telemed Telecare*. 2012;18:211–220.
- Seibert PS, Whitmore TA, Patterson C, et al. Telemedicine facilitates CHF home health care for those with systolic dysfunction. *Int J Telemed Appl*. 2008;2008:1–7.
- Kruse CS, Soma M, Pulluri D, et al. The effectiveness of telemedicine in the management of chronic heart disease - a systematic review. *J R Soc Med Open*. 2017;8:1–7.
- Van der Meij E, Anema JR, Otten RHJ, et al. The effect of perioperative e-health interventions on the postoperative course: a systematic review of randomised and non-randomised controlled trials. *PLoS One*. 2016;11:e0158612.
- Liberati A, Altman DG, Tetzlaff J, et al. Guidelines and guidance the PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *PLoS Med*. 2009;6:e1000100.
- Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. *J Epidemiol Community Heal*. 1998;52:377–384.
- Shalan A, Abdulrahman A, Habli I, et al. YORwalk: designing a smartphone exercise application for people with intermittent claudication. *Stud Health Technol Inform*. 2018;247:311–315.
- Alvarez Garcia J, Alvarez-Garcia JA, Fernandez-Heredero A, et al. Using the new technologies in claudication patients: cReTe: claudication patients and telematic register. *Angiologia*. 2015;67:101–106.
- Gunter R, Fernandes-Taylor S, Mahnke A, et al. Evaluating patient usability of an image-based mobile health platform for postoperative wound monitoring. *JMIR mHealth uHealth*. 2016;4:e113.
- Boyes R, Harris L. Pictures and telemedicine to promote communication and improve concordance in leg ulcer care. *Wounds UK*. 2009;5:67–75.
- Mercer K, Giangregorio L, Schneider E, et al. Acceptance of commercially available wearable activity trackers among adults aged over 50 and with chronic illness: a mixed-methods evaluation. *JMIR mHealth uHealth*. 2016;4:e7.
- Dhukaram AV, Baber C, De Stefanis P. Patient-centred cardiovascular disease management - end-user perceptions. *J Assist Technol*. 2012;6:105–122.
- Thomas DW, Wolfe R. A preliminary study on educating hospitalized geriatric vascular patients on the use of movement-induced computer games to improve exercise attitudes. *Act Adapt Aging*. 2017;41:129–137.
- Low CA, Bovbjerg DH, Ahrendt S, et al. Fitbit step counts during inpatient recovery from cancer surgery as a predictor of readmission. *Ann Behav Med*. 2018;52:88–92.
- Mousa AY, Davis E, Monnett S, et al. Results of telehealth electronic monitoring for post discharge complications and surgical site infections following arterial revascularization with groin incision [Internet]. *Ann Vasc Surg*. 2019;1–10. DOI:10.1016/j.avsg.2018.09.023.
- McDermott MM, Ades P, Guralnik JM, et al. Treadmill exercise and resistance training in patients with peripheral arterial disease with and without intermittent claudication: a randomized controlled trial. *JAMA*. 2009;301:165–174.
- Sutton M, Kreider K, Thompson J, et al. Improving outcomes in patients with peripheral arterial disease. *J Vasc Nurs*. 2018;36:166–172.
- Gardner AW, Parker DE, Montgomery PS, et al. Step-monitored home exercise improves ambulation, vascular function, and inflammation in symptomatic patients with peripheral artery disease: a randomized controlled trial. *J Am Heart Assoc*. 2014;3:1–11.
- Cornelis N, Buys R, Fourneau I, et al. Exploring physical activity behaviour – needs for and interest in a technology-delivered, home-based exercise programme among patients with intermittent claudication. *Vasa*. 2018;47:109–117.
- Zwaap J, Knies S, Meijden van der C, et al. Cost-effectiveness in practice. Diemen, the Netherlands: National Health Care Institute. 2015. Available from: <https://www.zorginstituutnederland.nl/binaries/content/documents/zinl-www/documenten/publicaties/rapporten-en-standpunten/2015/1506-kosteneffectiviteit-in-de-praktijk/Kosteneffectiviteit+in+de+praktijk.pdf>
- Greving JP, Kaasjager HAH, Vernooij JWP, et al. Cost-effectiveness of a nurse-led internet-based vascular risk factor management programme: economic evaluation alongside a randomised controlled clinical trial. *BMJ Open*. 2015;5:e007128.
- Normahani P, Kwasnicki R, Bicknell C, et al. Wearable sensor technology efficacy in peripheral vascular disease (wSTEP): a randomized controlled trial. *Ann Surg*. 2018;268:1113–1118.
- Davins Riu M, Borràs Pérez X, Artigas Raventós V, et al. Use of telehealth as a new model for following intermittent claudication and promoting patient expertise. *Telemed e-Health*. 2018;24:773–781.
- Gunter RL, Fernandes-Taylor S, Rahman S, et al. Feasibility of an image-based mobile health protocol for postoperative wound monitoring. *J Am Coll Surg*. 2018;226:277–286.
- McDermott MM, Spring B, Berger JS, et al. Effect of a home-based exercise intervention of wearable technology and telephone coaching on walking performance in peripheral artery disease: the honor randomized clinical trial. *JAMA*. 2018;319:1665–1676.
- Duscha BD, Piner LW, Patel MP, et al. Effects of a 12-week mHealth program on functional capacity and physical activity in patients with peripheral artery disease. *Am J Cardiol*. 2018;122:879–884.
- Joshi M, Ashrafian H, Aufegger L, et al. Wearable sensors to improve detection of patient deterioration. *Expert Rev Med Devices*. 2019;16:145–154.
- Weenk AM, Koenen M, van de Belt, T. H. Wireless and continuous monitoring of vital signs in patients at the general ward. *Resuscitation*. 2019;136:47–53.
- Dias D, Paulo Silva Cunha J. Wearable health devices-vital sign monitoring, systems and technologies. *Sensors (Basel)*. 2018;18:1–28.
- Downey CL, Chapman S, Randell R, et al. The impact of continuous versus intermittent vital signs monitoring in hospitals: a systematic review and narrative synthesis. *Int J Nurs Stud*. 2018;84:19–27.
- Michard F. Smartphones and e-tablets in perioperative medicine. *Korean J Anesthesiol*. 2017;70:493–499.
- Chen BP, Awasthi R, Sweet SN, et al. Four-week prehabilitation program is sufficient to modify exercise behaviors and improve preoperative functional walking capacity in patients with colorectal cancer. *Support Care Cancer*. 2017;25:33–40.
- Krupinski E, Bernard J. Standards and guidelines in telemedicine and telehealth. *Healthcare*. 2014;2:74–93.